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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,440	06/16/2006	Polonca Kuhar	33571-US-PCT 64654.US	3690

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EXAMINER	
KASSA, TIGABU	

ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
04/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/583,440	KUHAR ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 February 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ They raise the issue of new matter (see NOTE below);

   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-5,7-12,14 and 16*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619

Continuation of 11. The rejections of Claims 1-4, 7, 10, 12, 20, 22-26 and 28-29 have been rejected under 35 U.S.C. § 103(a) as being obvious over Vogel et al. (J. Macromol. Sci.-Chem. 1970, A4, 675-692) in view of Gratson et al. Langmuir 2005, 21,457-464 (IDS Reference) and all the other rejections of the dependent claims in the record would be overcome if the amendments were entered, but are maintained due to the reasons set forth below in 3(a) and 11.

Applicants' proposed claim amendments do not place the case in condition for allowance or in better condition for appeal. Applicants traversed this rejection on the grounds that claim 1 has been amended to recite a controlled release pharmaceutical formulation comprising a pellet core from which a low dosage of tamsulosin (or a pharmaceutically acceptable salt thereof) which is freely soluble in water can be released in a controlled manner independently from pH. In order to achieve this pH independent release of tamsulosin, at least one water insoluble permeable polymer is incorporated into the pellet core. Applicants' assert that Platteeuw's specific goal to formulate tamsulosin in pellet cores so that the release of the tamsulosin from the cores is "dependent upon the pH" See Platteeuw, column 3, lines 63 - 65. To that end, Platteeuw specifies the use of an "acid resistant acrylic polymer" in the pellet core at Col. 3, lines 63 - 64 and in Claim 1. These acid resistant polymers are "not soluble in acidic aqueous medium, while they are soluble in neutral or basis aqueous medium." See Platteeuw, column 4, lines 59 - 60. Since the pellet cores disclosed in Platteeuw comprise an acid resistant polymer which is "not soluble in acidic aqueous medium" but is "soluble in neutral or basis aqueous medium", Platteeuw clearly does not disclose a pellet core from which a low dosage oftamsulosin, or a pharmaceutically acceptable salt thereof, which is freely soluble in water can be released in a controlled manner independently from pH. The examiner respectfully disagrees with applicants' assertions because Platteeuw discloses a controlled release formulation of tamsulosin in a pellet core (abstract). Platteeuw discloses a pharmaceutical pellet composition comprising tamsulosin as an active ingredient and having an advantageous coating layer with respect to obtaining an extended release profile (column 2, lines 19-22). Each pellet comprises a pellet core, which has a diameter within the range of 0.3-0.9 mm, comprising tamsulosin hydrochloride, microcrystalline cellulose, a pharmaceutically acceptable water permeable acrylic polymer, and water (column 2, lines 24-28). Each pellet core is surrounded by an outer layer coat, which comprises a pharmaceutically acceptable acid-resistant acrylic polymer, in an amount, calculated on a dry pellet core basis, that is within the range of 2.5-15% (column 2, lines 28-32). A careful review of Platteeuw and applicants' original specification reveals that the water insoluble permeable polymer incorporated in the pellet core are exactly the same between the two formulations. Platteeuw discloses that within the invention, an "acrylic polymer" means a pharmaceutically acceptable copolymer of methacrylic acid and an acrylic or methacrylic acid ester, such as sold under brand name Eudragit (column 3, lines 51-54). The release of the active substance from the admixture with such acrylic polymers may or may not be dependent on the environmental pH (column 3, lines 57-59). Preferably, the polymer is an acid-resistant acrylic polymer, which releases tamsulosin dependent upon the pH and such polymers include Eudragit L products, especially Eudragit L 30 D for example Eudragit L 30 D-55 (column 3, lines 63-66). Applicants' original specification also discloses that "For release control, pellet cores can comprise different insoluble permeable polymers in the form of powders, granules or water dispersions which enable pH independent release of the active substance. We have surprisingly found that for this purpose, selected acrylic polymers are particularly suitable, such as polymers or copolymers of acrylic or methacrylic acid or esters of acrylic or methacrylic acid, optionally having functional groups, among them particularly copolymers of methacrylic esters with trimethylammonioethyl- or ammonioethyl- or similar functional groups, copolymers of methacrylic acid and methacrylic esters, copolymers of methacrylic esters, further different types of alkylcelluloses, such as e.g. ethylcellulose or methylcellulose or different combinations thereof." (page 4). The polymers taught by Platteeuw are the same as the polymers disclosed in applicants' specification. The examiner contends that the assertions of controlled release independently from pH and the teachings by Platteeuw release dependent upon the pH are differences in syntax not in composition content.

With regard to the obviousness rejections of Platteeuw in view of Chen applicants asserted the arguments set forth above. The examiner incorporates the rebuttal arguments set forth above by reference in this section too since they are equally applicable. Applicants further assert that "For a variety of reasons, the cited Chen reference cannot overcome these deficiencies in the Platteeuw patent. As an initial matter, Chen is directed to formulation for benzamidazoles, such as omeprazole. Chen does not disclose or suggest anything in regard to tamsulosin, which differs significantly from benzamidazoles like omeprazole in both its chemical structure and its resultant physical properties, and there would have been no incentive or motivation for a person of skill working on tamsulosin formulations to look to Chen for any relevant guidance, teaching, or other ideas vis-a-vis ways of formulating tamsulosin." The examiner respectfully disagrees with these assertions because for Chen to be proper prior art it does not have to teach tamsulosin as this limitation is clearly addressed by Platteeuw. Chen is solely incorporated for the teachings of polymer and surfactant in the formulation which is a relevant teaching that can be utilized in similar controlled release formulations comprising a pellet core containing an active coated with a controlled release layer. Applicants also argue that "Further, the dosage amounts of omeprazole disclosed in Chen do not correspond to the relatively low dosage amounts as called for in the present claims." The examiner respectfully disagrees with applicants' assertions because the low dosage form limitation is also addressed by Platteeuw. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).